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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/509,094

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Abdurrahman Mithat Bozdayi

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EXAMINER

KINSEY WHITE, NICOLE ERIN

ART UNIT

PAPER NUMBER

1648

MAIL DATE

DELIVERY MODE

05/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/509,094	Applicant(s) BOZDAYI, ABDURRAHMAN MITHAT	
	Examiner NICOLE KINSEY WHITE	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 and 38-40 is/are pending in the application.
 4a) Of the above claim(s) 31-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-12, 21-30 and 38-40 is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Withdrawn Rejections

The rejection of claims 13-16 and 21-24 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the presence of HBV in a sample by detecting polynucleic acid comprising the reverse transcriptase domain with a mutation at codon 204, wherein codon 204 is a serine, does not reasonably provide enablement for detecting the presence of HBV in a sample by detecting an HBV polynucleic acid or fragment comprising codon 204 of the reverse transcriptase domain, wherein codon 204 is a serine has been withdrawn in view of applicants' amendments to the claims.

The rejection of claims 1, 2, 4-6, 8-12 under 35 U.S.C. 102(b) as being anticipated by Petzold et al. (GenBank Accession No. AJ131956, Submitted 05-JAN-1999) has been withdrawn in view of applicants' amendments to the claims.

Claim Objections

Claims 1, 2, 11, 12, 14, 15, 18, 19, 21, 22, 25, 26 and 40 are objected to because of the following informalities: Claims 1, 2, 14, 15, 18, 19, 21, 22, 25, 26 and 40 should recite, for example, a serine encoding codon at position 204.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 13-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,422,848. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The patent claims are drawn to, *inter alia*, a method for detecting the presence of an HBV variant in a biological sample, comprising: a) obtaining a target HBV polynucleic acid from said biological sample wherein said target HBV polynucleic acid is suspected to comprise a serine-encoding codon 181 of the HBV reverse transcriptase domain, and optionally one or more of the codons chosen from the group consisting of a methionine-encoding codon 180, an isoleucine-encoding codon 204 or a valine-encoding codon 204

or a serine-encoding codon 204, and a threonine encoding codon 236 of the HBV reverse transcriptase domain of an HBV virus; b) obtaining the nucleic acid sequence of the target HBV polynucleic acid of (a); c) inferring, from the nucleic acid sequence obtained in (b), the presence of said serine-encoding codon 181 of the HBV reverse transcriptase domain, and optionally one or more codons chosen from the group mentioned in (a) and, therefrom, the presence of said HBV virus in said biological sample.

The instant claims are drawn to a method for detecting the presence of an HBV in a biological sample, said method comprising the step of detecting the presence of an HBV polynucleic acid comprising a reverse transcriptase encoding domain, said reverse transcriptase encoding domain comprising a serine encoding codon 204.

The patented claims anticipate the instant claims, and a patent to the instant genus claims would, necessarily, extend the rights of the already patented sub-genus claims should the instant genus claims issue as a patent.

Claims 1-12, 21-30 and 38-40 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NICOLE KINSEY WHITE whose telephone number is (571)272-9943. The examiner can normally be reached on Monday through Friday from 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicole Kinsey White/
Examiner, Art Unit 1648

/Stacy B Chen/
Primary Examiner, Art Unit 1648